

Response dated October 5, 2005
Reply to Office Action dated 8/25/2004

Application No. 09/561,064

REMARKS

The Final Office Action of May 19, 2005 has been reviewed and the comments therein were carefully considered. Claims 1, 9, and 40 have been amended by the current response. Claims 1-5, 7-9, and 40-49 are currently pending in the present application. No new matter has been introduced into the application.

Rejections under 35 USC §102

Claims 1-9 and 40-49 are rejected under 35 USC §102(b) as being anticipated by Snell U.S. Patent No. 5,456,691.

Applicants have amended claims 1, 9, and 40 to more particularly describe the invention.

Snell discloses a programmer in which a control program for an implantable medical device is constructed from program modules that are selected by a physician. (Abstract). The modules may be individually loaded into the implantable medical device or may be combined into a single program, without necessitating an increase in the memory capacity of the implantable device. (Col. 2; lines 7-10).

With regard to currently amended independent claim 1, Snell does not disclose, teach, or suggest at least the claimed feature of “accessing by a patient with the patient programmer via telemetry at least two preset clinician therapy programs stored in the medical device.” (Emphasis added). Support for the claimed feature of “accessing by a patient with the patient programmer” can be found beginning on page 11, line 8 which states:

In an embodiment of the present invention, as will be discussed below, a patient can access the preset clinician therapy programs (PCTP) stored in the INS via the patient programmer 50. The patient programmer 50 can comprise a graphical display screen 60, an input medium or device 70, a patient program controller 55, memory 75 and a telemetry block 65. Having accessed a PCTP, the patient can then create at least one personalized therapy from the accessed PCTP.

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The patient can then store the new personalized therapy program in the INS 5 via the patient programmer 50 input device 70.

... First, a patient would turn the patient programmer 50 ON and start the process in a first Start Screen. Second, the patient would select a Review function and interrogate the INS 5 via the input device 70. The patient would then select a Select Menu function that brings up a Selection Screen on the graphical display screen 60. The Selection screen would display a Menu indicating the various preset clinician therapy programs (PCTP) 170 (discussed in more detail with reference to Figure 5) that are resident in the INS memory 100. The patient could then scroll through the Menu (on the graphical display screen 60) and select the particular PCTP 170 that he/she wishes to access in order to create at least one personalized therapy program. Having accessed a PCTP 170, the patient can then review and modify the preset clinician therapy settings (PCTS) 180 (discussed in more detail with reference to Figure 5) that correspond to the accessed PCTP 170. The patient may then select and optimize a PCTS 180 as necessary or desired by use of the graphical display screen 60 and the input device 70.

As can be seen from at least the above cited section of the specification, a patient's commands and instructions are being implemented "with the patient programmer." It is respectfully submitted that Snell does not disclose, teach or suggest at least the claimed element of "accessing by a patient with the patient programmer . . ." Snell is concerned with loading of individual modules into memory of a device, without necessitating an increase in the memory capacity of the device. This loading of the individual modules is accomplished by a physician or trained specialist prior to any use by a patient. For example, Column 4, line 27 of Snell states:

The physician selects program modules corresponding to those therapies and diagnostic routines that are thought to be most effective for treating the patient at step 34 . . .

Applicants submit that there is no disclosure or suggestion in Snell of a patient using a "patient programmer" to access present clinical therapy programs.

Furthermore, claim 1 is allowable for at least an additional reason. Currently amended claim 1 includes the feature of "the at least one personalized therapy program based on patient activity." (Emphasis added). Snell does not disclose, teach, or suggest this claimed feature. In

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Snell, only a physician or trained specialist can construct control programs from program modules. The patient is not allowed to create or store any personalized therapy programs based on patient activity.

In contrast, Applicant's claimed invention "allows a patient to . . . modify the stored therapy programs to accommodate his/her particular lifestyle, thereby creating and storing personalized therapy programs." (Specification on Page 5, lines 20-23.

Therefore, for at least these reasons, it is respectfully submitted that claim 1 is patentably distinct over Snell. Dependent claims 2-8 are allowable for at least the same reasons as independent claim 1.

Similar to claim 1, independent claims 9 and 40 also contain the claimed features of "accessing by a patient with the patient programmer . . ." and "the at least one personalized therapy program based on patient activity." (Emphasis Added). Therefore for at least the same reasons discussed above with respect to claim 1, independent claims 9 and 40 are allowable. Dependent claims 41-49 which ultimately depend on claim 40 are allowable for at least the same reason as independent claim 40.

Claims 1-2, 4-5, 9 are rejected under 35 USC §102(b) as being anticipated by Ford et al., U.S. Patent No. 5,681,285.

Applicants have amended claims 1, and 9 to more particularly describe the invention.

Ford discloses a drug library containing a plurality of drug entries for use in a syringe pump. A standard drug library may be customized with additional drug entries through the use a personal computer (PC). (Col. 11, lines 30-33). The customized drug library containing the supplementary drug entries may be downloaded into the syringe pump and utilized to administer selected therapeutics. (Col. 11, lines 33-38).

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With regard to claim 1, Ford does not disclose, teach, or suggest a personalized drug therapy program "based on patient activity." (Emphasis added). Ford is concerned with creation of a drug library containing drug entries having infusion characteristics for particular drug: for use in a syringe pump, regardless of who the patient is or what activity the patient is engaged in.

Support for the claimed feature of "at least one personalized drug therapy program based on patient activity" may be found in the Specification on Page 12, Lines 10-22, which states:

Once the patient has created a personalized therapy program 190, a Save function can be selected. . . . For example, the user could label the just created personalized therapy program 190 a "Sleep" program. . . . The patient could repeat the above steps to create other personalized therapy programs 190, for example programs such as "Running", "Eating", "Sitting", "Exercising" and others.

As specified above, the creation of personalized therapy programs by patients may be based on a patient's particular activity at a specified moment in time. Such patient activities may include sleeping, running, eating, sitting, or exercising.

In addition, neither patent discloses, teaches, or suggests "creating at least one personalized drug therapy program by the patient from the modified at least one preset clinical drug therapy program, the at least one personalized drug therapy program based on patient activity." Ford is concerned with allowing a physician to select infusion characteristics for a particular drug. Not only is the physician unable to create programs based on patient activity, but also the patient cannot create and store programs based on his/her activity.

Therefore for at least these reasons, independent claims 1 and 9 are in condition for allowance. Dependent claims 2 and 4-5 which ultimately depend on claim 1 are allowable for at least the same reason as independent claim 1.

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Rejections under 35 USC §103

Claims 45 and 46 are rejected under 35 USC §103(a) as being unpatentable over Snell U.S. Patent No. 5,456,691.

Dependent claims 45 and 46 ultimately depend from independent claim 40. Applicant respectfully submits that independent claims 45 and 46 are allowable for at least the same reasons as independent claim 40 from which dependent claims 45 and 46 ultimately depend.

Applicants therefore respectfully request reconsideration of the pending claims and a finding of their allowability. A notice to this effect is respectfully requested. Please feel free to contact the undersigned should any questions arise with respect to this case that may be addressed by telephone.

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Respectfully submitted,

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